

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **16 JUN 2005**

FOR FURTHER ACTION
See paragraph 2 below

Applicant's or agent's file reference

062002-2910

International application No.

PCT/US04/38021

International filing date (day/month/year)

15 November 2004 (15.11.2004)

Priority date (day/month/year)

13 November 2003 (13.11.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C12Q 1/04; C12M 1/34 and US Cl.: 435/7.2, 287.2

Applicant

GEORGIA TECH RESEARCH CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-55, 59-73</u>	YES
	Claims <u>56-58, 74-82</u>	NO
Inventive step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-82</u>	NO
Industrial applicability (IA)	Claims <u>1-82</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 56-58 and 74-82 lack novelty under PCT Article 33(2) as being anticipated by Karube et al. The reference of Karube et al. discloses a system for detecting one or more target substances that includes a piezoelectric substrate (141) in a chamber (144) wherein the substrate includes a plurality of different binding agents so as to detect a plurality of different analytes. The system includes an input transducer (166) and an output transducer (167) and an operating system (168).

Claims 56-58 and 74-82 lack novelty under PCT Article 33(2) as being anticipated by Willner et al. The reference of Willner et al. discloses a system for detecting one or more target substances that includes a piezoelectric substrate in a chamber wherein the substrate includes a plurality of different binding agents so as to detect a plurality of different analytes. The system includes an input transducer and an output transducer and an operating system (See pages 12, 24 and 25).

Claims 59-66 lack an inventive step under PCT Article 33(3) as being obvious over Larue. The reference of Larue discloses that it is known in the art to employ a piezoelectric substrate for the detection of specific chemicals in a liquid. The reference discloses that any chemical species can be detected using the device as long as the analyte to be detected has a complementary that can be adsorbed onto the piezoelectric surface (See column 10, lines 15-37). In view of this disclosure and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to detect the presence of any chemical species of interest, such as a scaling agent, by merely providing the surface of the sensor with a complementary to the scaling agent to be detected.

Claims 1-58 and 67-82 lack an inventive step under PCT Article 33(3) as being obvious over Ebersole et al. in view of Willner et al. The reference of Ebersole et al. discloses a detection system and method of use that includes a culture chamber including a cellular attachment surface (See column 12, lines 11-61) wherein a piezoelectric oscillator is positioned near the attachment surface. While the system is disclosed a responding to metabolites produced by the cultured cells for identification and/or determination of the cells in response to drugs or other test chemicals, the reference discloses that binding agents are not provided on the piezoelectric oscillator so as to simplify manufacture of the device. The reference of Willner et al. discloses that it is conventional in the art to provide piezoelectric oscillators with binding agents. The reference discloses that a single oscillator can include a plurality of different binding agents. In view of these disclosures, it would have been obvious to one of ordinary skill in the art to provide the oscillators of the primary reference of Ebersole et al. with binding agents as is conventional in the art. Use of the binding agents that are specific to a specific metabolite would have been obvious for the known and expected result of eliminating the need to employ a metabolic product responsive polymer in the test system. Whether the test device is employed in the lab or provided at a remote location for monitoring and control of culture conditions would have been obvious for the known and expected result of employment of the system for its known and intended use of monitoring for the presence of microorganisms.

Claims 1-82 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 59-66 are objected to as lacking clarity under PCT Rule 66.2(a)(v) because of the claims not fully supported by the description. The description does not disclose the claimed invention in a manner sufficiently clear and complete for the claimed invention to be carried out by a person skilled in the art because: Claims 59-66 require the use of a binding agent that is capable of binding with a scaling agent. Specifically, binding with hexenuronic acid, catechol or aluminum sulfate. The prior art does not readily convey conventional binding agents for binding with scaling agent and/or the specific agents recited in the claims. Review of the specification fails to provide specific examples and/or list possible binding agents that can be employed to make and/or use the invention of the instant claims. In view of this lack of information in the specification and/or common knowledge in the art, the instant disclosure fails to enable one of ordinary skill in the art to make and/or use the instant application without undue experimentation to determine what binding agents could be used to enable the claimed invention.